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| APPLICATION NO.                 | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---------------------------------|-------------|----------------------|---------------------|------------------|
| 09/904,459                      | 07/16/2001  | Gilles Guichard      | 99 BB CNR URE       | 9090             |
| 466                             | 7590        | 03/05/2004           | EXAMINER            |                  |
| YOUNG & THOMPSON                |             |                      | KIFLE, BRUCK        |                  |
| 745 SOUTH 23RD STREET 2ND FLOOR |             |                      |                     |                  |
| ARLINGTON, VA 22202             |             |                      | ART UNIT            | PAPER NUMBER     |
|                                 |             |                      | 1624                |                  |

DATE MAILED: 03/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                       |                         |
|------------------------------|---------------------------------------|-------------------------|
| <b>Office Action Summary</b> | <b>Application No.</b>                | <b>Applicant(s)</b>     |
|                              | 09/904,459                            | GUICHARD ET AL.         |
|                              | <b>Examiner</b><br>Bruck Kifle, Ph.D. | <b>Art Unit</b><br>1624 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 23 December 2003.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 40-53 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 40-53 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                     | Paper No(s)/Mail Date. _____ .  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____ .                                  |

Applicant's amendments and remarks filed 12/23/03 have been received and reviewed.

Claims 40-53 are now pending in this application.

***Claim Rejections - 35 USC § 112***

Claims 40-53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- i) The value of "n" is open-ended. The variable is defined as "a whole number greater than or equal to 1" which is indefinite. Can "n" be 10? 100? 1000? The upper limit of "n" has to be given in the claims. The variable "i" depends on the value of "n" and is therefore also indefinite.
- ii) The group "GP" is defined as "a protective group selected from a hydrogen atom, an oxycarbonyl (ROCO), acyl, alkyl, aryl, urea, phthalimide (with R<sup>1</sup> = 0), biotin, O<sub>2</sub> (with R<sup>1</sup> = 0) group, or the "GP-N" entity forms an "NH<sub>2</sub>" entity." This definition is indefinite because hydrogen is not known to be a protecting group. A protecting group is added by removing hydrogen. The group "oxycarbonyl (ROCO)" is unclear as to what the rest of the radical is beyond the oxycarbonyl, i.e., the nature of "R" in R-C(O)-O- is not known. In "acyl", is only alkyl carbonyl intended or are acyls from sulfonic, phosphonic, arsenic acids, etc also intended? Urea is a compound and not a radical, is H<sub>2</sub>N-C(O)-NH- (ureido) intended? Similarly, it appears that Applicants intent that the group "GP" along with the nitrogen to which it is attached and R<sup>1</sup> form a phthalimido group. Biotin is a molecule with no open valency and cannot be a radical. If Applicants intend the radical, it is suggested to show the point of attachment. It is unclear what is intended by O<sub>2</sub>. Lastly, when the "GP-N" entity forms an "NH<sub>2</sub>" entity, the counter ion required is not present. Appropriate corrections and clarifications are required.

- iii) In the definitions of R<sup>1</sup> and R<sup>i</sup>, the phrase “an alkyl group whose cyclic structure contains 5 to 20 carbon atoms” is self-contradictory. An alkyl group does not have cyclic structures. Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term “alkyl” in claim 40 is used by the claim to mean “cycloalkyl”, while the accepted meaning is “non-cyclic chain.” The term is indefinite because the specification does not clearly redefine the term.
- iv) The metes and bonds of “X” is unclear. It has to be a radical. Is X limited to a phenol, optionally substituted by nitro, halo, hydroxylamino, ... imidazole or tetrazole or is it more. The claim language is ambiguous. Claim 41 does not support this. Appropriate correction is required.
- v) It is unclear what kind of a cycle is formed by of R<sup>1</sup> and R<sup>i</sup>. How many atoms are present? Which atoms are present? Is it a saturated, unsaturated or partially unsaturated cycle? Is it monocyclic or polycyclic? Spiro?
- vi) In claim 42, the groups R<sup>2</sup>, R<sup>4</sup> and R<sup>5</sup> are not defined.
- vii) Claims 43-45 and 47-51 lack antecedent basis in claim 40. Regarding claim 43, X is not permitted to be a N-hydroxysuccinimde group in claim 40. Regarding claims 44, 45 and 50, the substituents on the various alkyl and aryl groups lack antecedent basis in claim 40. Regarding claims 47-49 and 51, the groups Fmoc and Boc lack antecedent basis in claim 40.

There are some provisos at the end of claim 40. Are these present to avoid prior art? If so Applicants are urgently requested to point to these compounds in the prior art because the disclosure of such compounds, should they exist, is material to the examination of this application. For example, a compound of the proviso would render obvious the instant claim wherein n is 1 or 3 because it has been long established that structural relationship varying the size of a linking carbon chain - is per se obvious. Specifically, In re Shetty, 195 USPQ 753, In re Wilder, 195 USPQ 426 and Ex Parte Greshem 121 USPQ 422 all feature a compound with a C<sub>2</sub> link rejected over a compound with a C<sub>1</sub> link. Similarly, In re Chupp, 2 USPQ 2nd 1437 and In re Coes, 81 USPQ 369 have a C<sub>1</sub> link unpatentable over a C<sub>2</sub> link. Ex parte Ruddy 121 USPQ 427 has a C<sub>3</sub> link unpatentable over a C<sub>1</sub> link. Ex parte Nathan, 121 USPQ 349 found the insertion of a C<sub>2</sub>H<sub>4</sub> link obvious. In all of these cases, the variation was per-se obvious and did not require a specific teaching.

#### *Improper Markush Rejection*

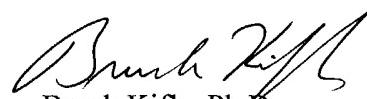
Claims 40-47, 50, 52 and 53 are rejected under a judicially created doctrine as being drawn to an improper Markush group, that is, the claims lack unity of invention. The basis of this rejection is the same as given in the previous office actions and is incorporated herein fully by reference. The claims lack "a community of chemical or physical characteristics" which justify their inclusion in a common group, which inclusion is not repugnant to principles of scientific classification" In re JONES (CCPA) 74 USPQ 149 (see footnote 2). The instant claims do NOT have a significant structural feature. The only fragment that is common is NH-C(O). This, however, is not a significant feature. This common structural feature of formula I, is **not** a patentable advance over the prior art.

The special technical feature is defined as meaning those technical features that define the contribution which each claimed invention, considered as a whole, makes over the prior art. The feature is, thus, not special if it is known.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruck Kifle, Ph.D. whose telephone number is 571-272-0668. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund J. Shah can be reached on 571-272-0674. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Bruck Kifle, Ph.D.  
Primary Examiner  
Art Unit 1624

BK  
March 3, 2004